AUG 22 2008

maine standards COMPANY, LLC

510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K082067."

Submitter: Maine Standards Company
Address: 765 Roosevelt Trail
Windham, ME 04062
Telephone: 207-892-1300
Fax: 207-892-2266
Contact: Holly A. Cressman, Mgr. QA/RA

Summary prepared on: July 10, 2008

Device classification name: Multi-Analyte Controls, All Kinds (Assayed and Unassayed)
Device description: Quality control material (assayed and unassayed)
Proprietary Name: MSC Lipid Control
Regulation Number: 21 CFR 862.1660
Product Code: JJY
Regulatory Class: Class I

Predicate Device:
Bio-Rad Liquichek™ Lipids Control Level 1 (K012513).

Device description: The MSC Lipid Control is a human serum based liquid control containing stabilized Cholesterol, Triglycerides, HDL Cholesterol and LDL Cholesterol of human origin.

Intended use: The MSC Lipid Control is intended for use as an assayed control material to monitor the ongoing precision of clinical laboratory analysis for Cholesterol, Triglycerides, HDL Cholesterol, and LDL Cholesterol. This material is intended for use on automated, semi-automated, and manual clinical chemistry analyzer systems.

Summary:
The information provided in this pre-market notification demonstrates that the performance of MSC Lipid Control is substantially equivalent in form and function to the predicate devices for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Maine Standards Co.
c/o Ms. Holly Cressman
765 Roosevelt Trail
Windham, ME 04062-5365

AUG 2 2 2008

Re: k082067
Trade Name: MSC Lipid Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I (reserved)
Product Codes: JJY
Dated: July 17, 2008
Received: July 22, 2008

Dear Ms. Cressman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K082067

Device Name: MSC Lipid Control

Indications For Use:

The MSC Lipid Control is intended for use as an assayed control material to monitor the ongoing precision of clinical laboratory analysis for Cholesterol, Triglycerides, HDL Cholesterol, and LDL Cholesterol. This material is intended for use on automated, semi-automated, and manual clinical chemistry analyzer systems.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K082067